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Summary

1.(SBU) The Taiwan Department of Health (DOH) Bureau of National Health Insurance (BNHI) will announce the results of the sixth price-volume survey (PVS) in July, and implement revised reimbursement prices in September. BNHI is following through on a Ma administration campaign promise to reform Taiwan's overall Pharmaceutical Benefits Scheme (PBS), and will finalize PBS guidance in July. Although original-drug manufacturers are unhappy with the current draft PBS reform, industry has failed to agree on a detailed counter-proposal.

¶2. (SBU) The Bureau of Pharmaceutical Affairs (BOPA) wants to speed up drug-approval times by reducing documentation requirements, but the proposed conditions for reduced documentation are insignificant, and will likely be little-used by drug-makers. Neither separation of dispensing and prescribing (SDP) nor patent linkage--two of industry's long-standing goals for Taiwan--have the support of Taiwan industry or bureaucracy, though a newly-established Taiwan Food and Drug Administration (TFDA) may make implementing patent-linkage in Taiwan more feasible. BNHI continues to press industry and AIT to support LY passage of a draft law requiring hospitals to use a standard drug-purchasing contract. End summary.

Pricing Background

¶3. (SBU) Taiwan implemented a National Health Insurance (NHI) system in 1995, and its health-care system comprises six large public medical centers, 16 large privately-owned medical centers, and 417 regional and district hospitals. The 22 large medical centers dominate the pharmaceutical market, and are able to negotiate very low drug prices. Hospitals derive up to half of these revenues from the difference between the lower prices they have negotiated with drug companies and the higher amounts that BNHI reimburses for the same drugs--the source of the so-called "Black Hole" in Taiwan's pharmaceuticals budget. BNHI, in turn, uses biannual price-volume surveys (PVS) to collect price data from hospitals and drug makers to use in calculating new, lower drug reimbursements.

6th PVS Underway, Big Pricing Reform Unlikely

¶4. (SBU) Taiwan law requires hospitals that accept reimbursements from BNHI to provide price data for all pharmaceutical purchases.

Foreign original-drug manufacturers, however, initially refused to supply pricing data in protest over past PVS methodology. After a pause in the PVS process to allow BNHI to collect views from industry, hospitals, and other stakeholders on reforming Taiwan's Pharmaceutical Benefits Scheme (PBS)--including hosting a December 2008 industry-wide conference--in February, BNHI again requested that companies submit pricing data.

¶5. (SBU) Lawyers for the foreign drug-makers' industry group in Taiwan, the International Research-based Pharmaceutical Manufactures Association (IRPMA), think BNHI does not have legal grounds to compel companies to submit price data. However, both IRPMA and AmCham Pharmaceutical Committee leaders asked member companies to do so as a show of industry's good will, and in March, all member companies submitted price data to BNHI. According to BNHI Vice President Lee Cheng-hua, the new reimbursement prices will go into effect on September 1.

¶6. (SBU) Foreign original-drug manufacturers fear the sixth PVS, like the five before it, will significantly reduce reimbursements for their drugs, as well as start another round of price-cut demands from the large hospital groups. Foreign firms, however, have been unable to reach consensus on how to respond concretely to BNHI's PVS methodology. They will discuss instead their ideas on reforming the overall PBS, and their plans to commission an economic model on pharma pricing reform in Taiwan.

PBS Reform Request Backfires

7.(U) In response to a Ma campaign promise to reform Taiwan's overall Pharmaceutical Benefits Scheme (PBS) and resolve the price

gap problem, BNHI hosted a one-day drug-pricing conference on December 31, 2008. Representatives from all eight major drug industry groups plus AmCham attended the conference, which produced a PBS reform outline now under study by BNHI.

¶8. (SBU) Over the following months, however, BNHI made no moves to implement the proposed changes. In May, IRPMA sent a petition to DPP Legislator and former DOH Minister Twu Shiing-zher requesting Twu push BNHI to move forward on PBS reform. Soon afterwards, Twu asked DOH Deputy Minister Cheng Shou-hsia to work with industry to finalize within three months a benefit scheme reform proposal, and, in late May, the Legislative Yuan (LY) Health and Environment Committee passed a Twu-backed non-binding resolution calling for the same.

¶9. (SBU) In response to the LY pressure, BNHI notified industry in May that the Bureau plans to produce a final PBS reform plan in July, and asked for industry's input on the current draft plan. However, despite a series of industry-BNHI meetings over the past month, U.S. and other original-drug makers have failed to reach consensus on industry's PBS reform counter-proposal. On June 5, BNHI again informed AmCham and PhRMA representatives that the Bureau will finalize the plan by mid-July, with or without industry input.

Proposed CPP Changes Not an Improvement

¶10. (U) A Certificate of Pharmaceutical Product (CPP) is a document provided either directly by the manufacturer or by the release country to attest that a drug has been approved for use in the release country, has been manufactured in compliance with food and drug safety in that country, and is labeled in the same manner as in the original country. In most cases, drug manufacturers will supply a CPP from a developed economy such as the United States or European Union market to the drug-approval authorities in a second market in order to demonstrate the drug is already for sale in another market, and thereby reduce the time and paperwork needed to gain approval for sale in the second market.

¶11. (U) When a pharmaceutical company applies for regulatory approval to market a drug in a country, the authorities in that country typically ask manufacturers to supply one CPP as proof that the drug is approved for sale in another market. Taiwan, however, requires CPPs from two countries. The two-CPP requirement

disadvantages U.S. firms because BOPA regards a CPP from the European Union as the equivalent of multiple CPPs, while the same document from the United States counts only as one CPP. In addition, although CPPs from all countries follow a standard, WHO-approved format, Taiwan requires notarization of CPPs by the Taiwan representative office in the CPP-issuing country.

¶12. (U) For the past two years, original-drug manufactures have been urging the DOH Bureau of Pharmaceutical Affairs (BOPA) to reduce the required number of CPPs to one in order to shorten the drug-approval process. In response, BOPA recently announced plans to reduce the number of required CPPs from two to one if the manufacturer conducts two phases of clinical trials in Taiwan for the drug in question. [Note: Pharmaceutical companies conduct clinical trials to gather data on the safety and efficacy of new drugs or new indications for old drugs. Typically, three phases are needed before a country's drug authorities will grant approval, with each successive phase including a larger group of subjects. End note.]

¶13. (SBU) The deadline to submit public comments on the proposed changes was June 8. BOPA's Dr. Liao told econoff on June 5 that since the CPP requirement is an administrative guideline and not a law, once DOH decides on the final rule change, BOPA will be able to post the requirement within two weeks.

¶14. (SBU) However, local general managers of American drug companies tell us that because Taiwan is a relatively small market, companies are unlikely to conduct extra trials in Taiwan just to take advantage of the reduced CPP requirement. Instead, the companies will simply wait for a second country to issue a CPP for the drug and then apply for Taiwan approval. In addition, because BOPA's plan would increase the required number of trial subjects for some of the phases, the change will often make doing clinical trials in Taiwan less attractive.

¶15. (SBU) IRPMA member companies instead propose relaxing the requirement to one CPP if the company performs one phase of trials in Taiwan, or waiving the CPP requirement completely if a company conducts two clinical trials in Taiwan. On June 5, econoff discussed these alternatives with Dr. Liao, who agreed the latter change would be more attractive for companies, and urged manufacturers to take

advantage of the public comment period to submit their ideas.

Still Little Support for SDP

¶16. (SBU) Currently, when a patient sees a doctor in a Taiwan hospital, the patient will almost always fill his prescription at the pharmacy owned by and located in the hospital. Because Taiwan's hospitals get much of their revenues from the difference between the lower prices they have negotiated with drug companies and the higher amounts that BNHI reimburses for the same drugs (ref A), hospital administrators and doctors have an incentive to both over-prescribe and push down contract prices for drugs. Separating dispensing and prescribing (SDP) would eliminate this incentive.

¶17. (SBU) The U.S. and Taiwan discuss SDP under the bilateral Trade and Investment Framework Agreement (TIFA), and Taiwan has done some small-scale SDP pilot programs. However, Taiwan's powerful hospitals and doctors' associations do not support any move toward SDP because it would sap hospitals' revenues. During a recent AIT-hosted roundtable on SDP, hospital administrators and doctors again objected loudly to any such moves, and BOPA is not actively planning larger SDP initiatives. Any progress toward SDP will require continued high-level engagement with the Taiwan authorities.

Bureaucracy Opposes Patent Linkage

¶18. (SBU) Taiwan lacks a patent-linkage notification requirement and allows generic-drug licensing before patent expiry, practices that foreign pharmaceutical manufacturers claim allow local generic drug makers to infringe on patent-holders' rights, as well as secure a

higher initial reimbursement price from BNHI (ref B).

¶19. (SBU) The U.S. and the Taipei American Chamber of Commerce have pushed the Taiwan authorities to implement a U.S.-style patent-linkage system that would continue to allow generic-drug testing before the original drug's patent expiration, but would include protections for the patent-holder's IPR and prevent generic-drug makers from licensing a generic form of a patented drug while the original patent is still valid.

¶20. (SBU) The Taiwan pharmaceutical authorities, however, do not want to implement a U.S.-style patent linkage system. On June 5, BOPA Director General Chi-chou Liao reiterated to econoff that BOPA does not think Taiwan needs to introduce patent linkage, since Taiwan's court system, including the specialized Intellectual Property (IP) Court (ref C) can efficiently resolve such IPR disputes. As evidence, Liao pointed to a recent case in which Pfizer sued several local firms for releasing generic versions of Pfizer's Lipitor prior before the original drug's patent expired. Although Pfizer lost, Liao said the case shows the specialized court can effectively handle drug-related IPR disputes.

BNHI Wants Industry, U.S. Support for Mandatory SC

¶21. (SBU) In response to U.S. concerns about the lack of transparency in drug procurement by Taiwan hospitals, during the 2007 TIFA meetings in Washington, Taiwan committed to implementing a mandatory standard contract (SC) that would require all hospitals to use the same contract for all drug purchases (ref D).

¶22. (SBU) In September 2007, the Taiwan Executive Yuan(EY) forwarded to the Legislative Yuan (LY) draft legislation that would require hospitals to use an SC for pharmaceutical purchases. If the law passes, BNHI would then finalize the text of the contract by administrative order. The current draft SC would require full disclosure of the actual price and allow the Bureau of National Health Insurance (BNHI) to more accurately establish real transaction prices in their price surveys.

¶23. (SBU) According to IRPMA Chief Operating Officer Carol Cheng, hospitals do not support the current BNHI draft SC because it would bring more transparency to their current pricing practices, potentially reducing the pricing gap that funds their operations. Foreign original-drug manufacturers also object to the proposed SC language, which would codify a practice whereby hospitals automatically renegotiate price contracts with drug companies whenever BNHI announces new, lower prices.

¶24. (SBU) Without industry or hospital support, the draft

legislation authorizing SC has languished in the LY since 2007. Acting BNHI President Lee has repeatedly asked IRPMA and member companies, as well as AIT, to lobby the LY for the proposed changes.

Comment

¶25. (SBU) Because Taiwan has no major new-drug makers, hospitals that rely heavily on profits from BNHI drug reimbursements, and consumers who are largely satisfied with the current system, there is limited domestic support for reforming pricing practices. In addition, with an economy in the doldrums and the national health care system at least USD two billion in the red (ref E), financial pressures will undercut any near-term move to spend more on reimbursement for on-patent drugs, or increase hospital funding in conjunction with implementing SDP.

¶26. (SBU) Therefore, the U.S.' pharma priority in Taiwan should be support for low-cost reforms such as passing the draft standard contract (SC) legislation and implementing patent linkage. While U.S. industry dislikes BNHI's current SC language, the U.S. should support passage of the bill authorizing BNHI to require that hospitals use SCs, while working with industry and the authorities

to improve the draft SC language. Because SC is one of two pharma-related TIFA topics, supporting SC plans could create momentum within BNHI for addressing other pharma issues under the TIFA rubric. In addition, although the Taiwan health bureaucracy does not favor implementing patent linkage, the upcoming merger of the DOH Bureau of Food Safety, Bureau of Pharmaceutical Affairs, Bureau of Food and Drug analysis, and the National Bureau of Controlled drugs into the Taiwan Food and Drug Administration (TFDA) offers a chance for fresh engagement with new TFDA leadership.

¶27. (SBU) In the longer term, the U.S. should encourage Taiwan to foster the policies and environment needed to commercialize Taiwan's nascent biotech and biomedical industries. The authorities have long identified biotech as a future strength of the Taiwan economy (refs F and G), and an indigenous biotech industry developing innovative drugs could kindle Taiwan interest in positive pharmaceutical pricing and IP reforms. End comment.

YOUNG